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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,203	07/30/2001	Jason Affourtit	PC10704ADAM	2144

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Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	6

DATE MAILED: 09/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/918,203	AFFOURTIT ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4 .	6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarkar et al (Biotechniques (1991) 10(4):436-438) in view of Lawyer et al (PCR Meth. App. (1993) 2:275-287).

Sarkar teaches a method for determining haplotype in a template DNA sequence comprising a first and second polymorphic marker (abstract) comprising:

(i) combining in a single reaction tube said template DNA sequence, forward primers that are allele specific for a first polymorphic marker, reverse primers that are

allele specific for a second polymorphic marker, and a DNA polymerase (page 436, columns 2 and 3),

(ii) conducting a polymerase chain reaction amplification in said tube to produce an amplification product (page 436, column 3),

(iii) analyzing the amplification product to identify which pair of said forward and reverse primers generated said amplification products (page 436, column 3 and page 437, figure 2),

wherein the haplotype is determined by the identification of said forward and reverse primer pair (see page 437, table 1 and figure 1).

Sarkar does not teach the use of the Stoffel fragment type polymerase.

Lawyer teaches the use of the Stoffel fragment type polymerase in allele specific amplification (see abstract and page 285, column 3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the Stoffel fragment in the place of Taq in the Allele specific amplification method of Sarkar since Lawyer states "The lower processivity of the Stoffel fragment also makes the enzyme useful for the amplification of rare mutant alleles in a background of normal DNA using allele specific primers where 3' mismatch extension is suppressed relative to that of full length Taq Pol I (page 285, column 3)". An ordinary practitioner would have been motivated to use the Stoffel fragment of Lawyer in the allele specific amplification method of Sarkar since Lawyer expressly teaches that the Stoffel fragment is desirable in allele specific amplification because 3' mismatch extension is suppressed.

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarkar et al (Biotechniques (1991) 10(4):436-438) in view of Lawyer et al (PCR Meth. App. (1993) 2:275-287) as applied to claim 1 and further in view of Iwahana et al (Human Genetics (1992) 90:325-326).

Sarkar in view of Lawyer teach the PASA method using the Stoffel fragment of claim 1 as discussed above.

Sarkar in view of Lawyer do not teach combining PASA with RFLP analysis.

Iwahana teaches combining PASA and RFLP (abstract, page 325, column 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the PASA method using the Stoffel fragment of Sarkar in view of Lawyer with the use of RFLP since Iwahana states "A new polymorphism of the human prothrombin (F2) gene was detected by a combination of polymerase chain reaction (PCR) amplification of specific alleles (PASA) and mutated primer-mediated PCR restriction fragment length polymorphism (PCR-RFLP). The method is simple and useful for detecting polymorphisms and mutations (abstract)". An ordinary practitioner would have been motivated to combine RFLP analysis with the PASA method of Sarkar in view of Lawyer since Iwahana teaches the combination of PASA and RFLP creates a simple method which is useful for detecting polymorphisms and mutations.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarkar et al (Biotechniques (1991) 10(4):436-438) in view of Lawyer et al (PCR Meth. App. (1993)

2:275-287) as applied to claim 1 and further in view of Zschocke et al (Mol. Cell. Probes (1995) 9:447-451).

Sarkar in view of Lawyer teach the PASA (ARMS is another name for the PASA method) method using the Stoffel fragment of claim 1 as discussed above.

Sarkar in view of Lawyer do not teach using fluorescently labeled primers.

Zschocke teaches the use of fluorescently labeled primers (abstract), of which some differ at the 5' end (see page 448, table 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the PASA (ARMS) method using the Stoffel fragment of Sarkar in view of Lawyer with the use of fluorescently labeled primers since Zschocke states "The fluorescent multiplex ARMS method is very specific, not least because of coamplification of normal and mutant alleles. Intrinsic control is further increased by multiplex amplification of different sites (page 450, column 1)". Zschocke also notes "The fluorescent multiplex ARMS approach is a useful first step in routine mutation analysis, particularly in a population where a few common mutations are found together with a large number of rare mutations. The method is simple, fast, inexpensive and is particularly well suited to the frequent analysis of few samples (page 450, column 2)". An ordinary practitioner would have been motivated to use fluorescent primers as taught by Zschocke in the PASA (ARMS) method of Sarkar in view of Lawyer since Zschocke notes that the use of fluorescent labels in the multiplex assay makes it simple, fast, useful, specific, well controlled and inexpensive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1637

September 13, 2002